

DSJ1&2-PR Exh 542

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA	:	
v.	:	CRIMINAL NO.
CEPHALON, INC.	:	

GUILTY PLEA AGREEMENT

Under Federal Rule of Criminal Procedure 11(c)(1)(C), the government, the defendant, Cephalon, Inc. (hereinafter "Cephalon"), and Cephalon's counsel enter into the following guilty plea agreement. Any reference to the United States or the government in this agreement shall mean the Office of the United States Attorney for the Eastern District of Pennsylvania, and the Office of Consumer Litigation of the Department of Justice.

1. Cephalon agrees to plead guilty to Count One of an Information, waiving prosecution by indictment, charging it with the introduction into interstate commerce of drugs that were misbranded through off-label promotion, a misdemeanor, in violation of 21 U.S.C. §§ 331(a), 333(a)(1) and 352(f)(1), and not to contest forfeiture as set forth in the notice of forfeiture seeking criminal forfeiture of \$10,000,000 in substitute assets, in lieu of the drugs which were promoted off-label and are no longer available, all arising from Cephalon's off-label promotion of its drugs Provigil, Gabitril, and Actiq between January 2001 and October 1, 2001. Cephalon further acknowledges its waiver of rights, as set forth in the attachment to this agreement.

2. The parties agree that this plea agreement is made pursuant to Fed.R.Crim.P. 11(c)(1)(C) and that the following specific sentence is the appropriate disposition

of this case. If the Court rejects this plea agreement, the parties further agree that this agreement shall automatically convert to a plea agreement pursuant to Fed.R.Crim.P. 11(c)(1)(B), and this specific sentence shall be the joint recommendation of the parties, although not binding on the Court. The agreed upon sentence is as follows:

A. Cephalon agrees to pay the special assessment in the amount of \$125 on the date of sentencing.

B. Cephalon agrees to pay \$50,000,000 to resolve this Information, of which \$40,000,000 will be applied to a criminal fine, and \$10,000,000 will be applied as substitute assets to satisfy the forfeiture obligation. Cephalon will pay these amounts within 10 business days of the date of sentencing. Cephalon and the government agree that this fine and forfeiture represent a fair and just resolution of all issues associated with loss, fine and forfeiture calculations.

C. Cephalon agrees that as a result of its acts or omissions, the forfeitable property, that is the drugs which were promoted off-label, are no longer available for forfeiture as they cannot be located or have been transferred, sold or deposited with a third party, or otherwise disposed of, within the meaning of federal law. As a result, Cephalon agrees to the entry and satisfaction of a judgment and preliminary order of forfeiture on the date of the guilty plea, forfeiting to the United States the sum of \$10,000,000 as substitute assets for the pertinent drugs. Cephalon agrees that, within 10 business days of the date of sentencing, Cephalon will make payment to the United States, by means of a wire transfer to the United States Marshal Service or check payable to same, in the amount of \$10,000,000, this amount representing

substitute assets of the offense for which it is pleading guilty, subject to forfeiture in full satisfaction of the judgment and preliminary order of forfeiture.

D. The government agrees that, in light of the Corporate Integrity Agreement executed contemporaneously with this guilty plea agreement, Cephalon will not be placed on probation.

3. In a separate civil settlement among Cephalon, the United States and various States, executed contemporaneously with this guilty plea agreement, Cephalon will pay \$375,000,000. Cephalon waives any and all defenses and objections in this matter or in that civil proceeding which might be available under the Double Jeopardy and Excessive Fines clauses of the Eighth Amendment. The parties agree that, in light of this civil settlement, and to avoid complicating and prolonging the sentencing process, the appropriate disposition of this case does not include a restitution order.

4. Cephalon waives any claim under the Hyde Amendment, 18 U.S.C. § 3006A (Statutory Note), for attorney's fees and other litigation expenses arising out of the investigation or prosecution of this matter.

5. Cephalon understands, agrees and has had explained to it by counsel that the Court may impose the following statutory maximum sentence: a fine of \$200,000, or twice the gross gain or gross loss, whichever is greater; a special assessment of \$125; restitution as ordered by the Court; and a five-year term of Court supervision; in addition, forfeiture may be ordered. Cephalon further understands that the terms and conditions of any Court supervision may be changed, and extended, by the Court if Cephalon violates any of the terms and conditions of that supervision.

6. With respect to Cephalon's conduct:

A. The parties stipulate to the following facts and basis for the plea, criminal fine and forfeiture:

- (1) Cephalon marketed Provigil, Gabitril, and Actiq, which were drugs within the meaning of 21 U.S.C. § 321(g)(1).
- (2) Shipments of a drug in interstate commerce must be accompanied by labeling bearing adequate directions for use for each of the drug's intended uses.
- (3) In 1998, Provigil was approved by the FDA to treat excessive daytime sleepiness associated with narcolepsy.
- (4) Between January 2001 and October 1, 2001, Cephalon promoted Provigil for uses not approved by the FDA, including as a daytime stimulant to treat sleepiness, tiredness, decreased activity, lack of energy and fatigue. Cephalon's promotion of Provigil for these additional intended uses violated 21 U.S.C. § 352(f)(1), because Provigil's labeling did not bear adequate directions for each of the drug's intended uses.
- (5) In 1997, Gabitril was approved by the FDA as an anti-epilepsy drug indicated as adjunctive therapy in adults and children 12 years and older in the treatment of partial seizures.
- (6) Between January 2001 and October 1, 2001, Cephalon promoted Gabitril for certain uses not approved by the FDA, including as an

agreement and Corporate Integrity Agreement are not executed contemporaneously with this plea agreement.

8. The government agrees that, other than the charges in the Information in this case, it will not bring any other criminal charges against Cephalon for conduct which (a) falls within the scope of the grand jury investigation in the Eastern District of Pennsylvania relating to Cephalon's drugs Provigil, Gabitril, and Actiq; or (b) was known to the United States Attorney's Office for the Eastern District of Pennsylvania and the Office of Consumer Litigation of the Department of Justice as of the date of the execution of this plea agreement, and which concerned the sale, promotion, or marketing of these three drugs in the United States. The non-prosecution provisions of this paragraph are binding on the Office of the United States Attorney for the Eastern District of Pennsylvania, the Office of Consumer Litigation of the Department of Justice, the United States Attorney's Offices for each of the other 93 judicial districts of the United States, and the Criminal Division of the United States Department of Justice. Attached as Exhibit B is a copy of the letter to United States Attorney Laurie Magid from the Assistant Attorney General, Criminal Division, Department of Justice, authorizing this agreement.

9. Cephalon understands that this guilty plea agreement does not bind any other government agency, or any component of the Department of Justice except as specified in paragraph 8 of this guilty plea agreement. Further, Cephalon understands that the United States takes no position as to the proper tax treatment of any of the payments made by Cephalon pursuant to this plea agreement, the civil settlement agreement, or the Corporate Integrity Agreement referenced in this plea agreement.

10. Cephalon agrees to waive the statute of limitations, and any other time-related defense, to the charge to which it is agreeing to plead guilty under this plea agreement. Cephalon understands and agrees that, should it seek to withdraw its plea, it may then be prosecuted for any criminal violation of which the United States has knowledge arising out of this investigation, subject to any applicable statute of limitation or other time-related protection not waived in this paragraph. Cephalon agrees that if it does not enter its plea, or withdraws its plea, after signing this agreement, the time period between the signing of this agreement and its withdrawal shall be excluded from calculation of the limitations or time period.

11. In exchange for the undertakings made by the government in entering this plea agreement, Cephalon voluntarily and expressly waives all rights to appeal or collaterally attack the defendant's conviction, sentence, or any other matter relating to this prosecution, whether such a right to appeal or collateral attack arises under 18 U.S.C. § 3742, 28 U.S.C. § 1291, 28 U.S.C. § 2255, or any other provision of law. This waiver is not intended to bar the assertion of constitutional claims that the relevant case law holds cannot be waived.

If this plea agreement converts to a plea agreement pursuant to Fed.R.Crim.P.

11(c)(1)(B):

- A. Notwithstanding the waiver provision above, if the government appeals from the sentence, then the defendant may file a direct appeal of its sentence.
- B. If the government does not appeal, then notwithstanding the waiver provision set forth in this paragraph, the defendant may file a direct appeal but may raise only claims that:

- (1) the defendant's sentence on any count of conviction exceeds the statutory maximum for that count as set forth in this plea agreement;
- (2) the sentencing judge erroneously departed upward pursuant to the Sentencing Guidelines; and/or
- (3) the sentencing judge, exercising the Court's discretion pursuant to United States v. Booker, 543 U.S. 220 (2005), imposed an unreasonable sentence above the final Sentencing Guideline range determined by the Court.

If the defendant does appeal pursuant to this paragraph, no issue may be presented by the defendant on appeal other than those described in this paragraph.

12. Cephalon also waives all rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including without limitation any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, or the Privacy Act, 5 U.S.C. § 552a.

13. Cephalon is satisfied with the legal representation provided by its lawyers; Cephalon and its lawyers have fully discussed this guilty plea agreement; and Cephalon is agreeing to plead guilty because Cephalon admits that it is guilty.

14. Cephalon will acknowledge acceptance of this guilty plea agreement by the signature of its counsel and of a responsible corporate officer. Cephalon shall provide to the government for attachment to this plea agreement a notarized resolution by Cephalon's Board of


Directors authorizing the corporation to enter a plea of guilty, and authorizing that responsible corporate officer to execute this agreement.

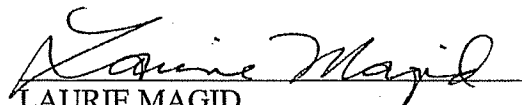
15. If acceptable to the Court, the parties agree to waive the presentence investigation and report pursuant to Rule 32(c)(1) of the Federal Rules of Criminal Procedure, and ask that Cephalon be sentenced at the time the guilty plea is entered.

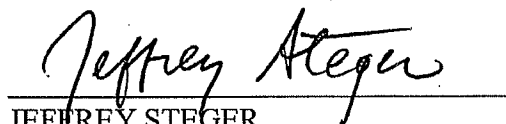
16. It is agreed that the parties' guilty plea agreement contains no additional promises, agreements or understandings other than those set forth in this written guilty plea agreement, and that no additional promises, agreements or understandings will be entered into unless in writing and signed by all parties.

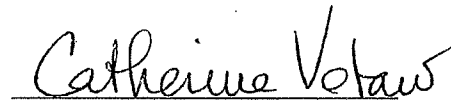
SIGNATURES FOR THE UNITED STATES

GREGORY G. KATSAS
Assistant Attorney General
Civil Division
United States Department of Justice


EUGENE THIROLF
Director, Office of Consumer Litigation
United States Department of Justice


LAURIE MAGID
Acting United States Attorney



JEFFREY STEGER
Trial Attorney
Office of Consumer Litigation
United States Department of Justice


CATHERINE VOTAW
Chief, Health Care Fraud
Assistant United States Attorney

DATED: Sept. 26, 2008

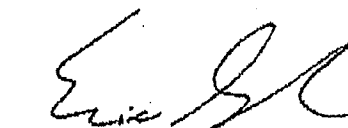
SIGNATURE FOR CEPHALON

DATE: 9/15/08


GERALD J. PAPPERT
Executive Vice President and General
Counsel
Cephalon, Inc.

SIGNATURES OF CEPHALON'S ATTORNEYS

DATE: 9/10/08


ERIC W. SITARCHUK, Esquire
Morgan, Lewis & Bockius LLP
Counsel for Defendant

J. SEDWICK SOLLERS III, Esquire
MARK A. JENSEN, Esquire
King & Spalding, LLP
Counsel for Defendant

Attachment

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA :
 :
 v. : CRIMINAL NO.
 :
 CEPHALON, INC. :

ACKNOWLEDGMENT OF RIGHTS

Cephalon, Inc. ("Cephalon"), through its properly authorized officer, hereby acknowledges that it has certain rights that it will be giving up by pleading guilty.

1. Cephalon understands that it does not have to plead guilty.
2. Cephalon may plead not guilty and insist upon a trial.
3. At that trial, Cephalon understands:
 - a. that Cephalon would have the right to be tried by a jury that would be selected from the Eastern District of Pennsylvania and that along with its attorney, Cephalon would have the right to participate in the selection of that jury;
 - b. that the jury could only convict Cephalon if all twelve jurors agreed that they were convinced of Cephalon's guilt beyond a reasonable doubt;
 - c. that the government would have the burden of proving Cephalon's guilt beyond a reasonable doubt and that Cephalon would not have to prove anything;
 - d. that Cephalon would be presumed innocent unless and until such time as the jury was convinced beyond a reasonable doubt that the government had proven that Cephalon was guilty;
 - e. that Cephalon would have the right to be represented by a lawyer at this trial and at any appeal following the trial, and that if Cephalon could not afford to hire a lawyer, the court would appoint one for Cephalon free of charge;

- f. that through Cephalon's lawyer Cephalon would have the right to confront and cross-examine the witnesses against Cephalon;
- g. that Cephalon could call witnesses to testify in its defense if Cephalon wanted to, and Cephalon could subpoena witnesses for this purpose if Cephalon wanted to; and
- h. that Cephalon would not have to call witnesses to testify or otherwise present any defense if Cephalon did not want to, and that if Cephalon did not present any evidence, the jury could not hold that against Cephalon.

4. Cephalon understands that if Cephalon pleaded guilty, there will be no trial and Cephalon would be giving up all of the rights listed above, as well as any other rights associated with the trial process arising under statute, common-law, or judicial precedent.

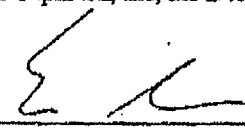
5. Cephalon understands that if Cephalon decides to enter a plea of guilty, the judge will ask Cephalon representatives questions under oath, and that if any of those representatives lie on behalf of Cephalon in answering those questions, those persons could be prosecuted for the crime of perjury, that is, for lying under oath.

6. Cephalon understands that if Cephalon pleads guilty, Cephalon has waived its right to appeal, except as set forth in appellate waiver provisions of the plea agreement.

7. Understanding that Cephalon has all these rights and that by pleading guilty Cephalon is giving them up, Cephalon still wishes to plead guilty.

 9/15/08
GERALD J. PAPPERT

Exec. Vice President and General Counsel
for Cephalon, Inc, the Defendant


ERIC SITARCHUK, Esquire
Morgan, Lewis & Bockius LLP
Counsel for Defendant.



U.S. Department of Justice

Criminal Division

Assistant Attorney General

Washington, D.C. 20530

AUG 28 2008

The Honorable Laurie Magid
United States Attorney
Eastern District of Pennsylvania
Philadelphia, Pennsylvania 19106

Attention: Catherine Votaw
Assistant United States Attorney

Re: Global Non-prosecution Agreement for Cephalon, Inc.

Dear Ms. Magid:

This is in response to your request for authorization to enter into a global case disposition agreement with the company Cephalon, Inc.

I hereby approve the terms of the Plea Agreement, including Paragraph 8, in which the United States Attorney's Offices and the Criminal Division of the Department of Justice agree not to initiate further criminal prosecutions as set out therein.

You are authorized to make this approval a matter of record in this proceeding.

Sincerely,

Matthew W. Friedrich
Acting Assistant Attorney General



John C. Keeney
Deputy Assistant Attorney General
Criminal Division

EXHIBIT B